

SPL Medical Device Subteam Meeting Minutes

Teleconference

May 21, 2009

Attendees:

Name	Affiliation	E-mail Address
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Agenda:

I. Review of the last meeting minutes (January 2008)

Meeting notes were reviewed from the January 10, 2008 meeting with David Racine (CDRH Office of Compliance) regarding SPL for medical devices.

II. Review developments from the HL7 January 2009 WG Meeting

Meeting notes were reviewed from the Regulated Clinical Research Management (RCRIM) Health Level Seven (HL7) Working Group Meeting in Orlando FL (January 11, 2009 -- January 16, 2009). Discussions included possible data elements that could be used for medical devices. The SPL system currently used for drugs and biologics could eventually be used for medical devices.

III. Terrie Reed (FDA CDRH) -- discussion on the FDA UDID Solution Overview document (attached)

Terry Reed presented the *UDID Solution Overview* document to the team for review and comments. Terrie requested that the team submits written comments by early June. Everyone is encouraged to submit comments to the SPL Medical Device Subteam. Please send your comments to Myron Finseth on or before June 3rd. Comments will be combined into one list and finalized during the next SPL Medical Device Subteam meeting on June 4th. The finalized list will be sent to Terrie before June 8th.

Terrie noted that the UDI attributes are similar to the SPL data elements.

IV. Q and A

The formal written questions and the responses will function as this agenda item.

V. Discuss future team activities (meetings)

Next team meeting will be scheduled for Thursday, June 4, 2009. Primary agenda item will be to finalize the list of UDI questions.

Find the SPL Working Group WIKI at:

<http://spl-work-group.wikispaces.com/Device>